

RULES AND REGULATIONS
RELATING TO
QUALITY ASSURANCE STANDARDS
FOR MAMMOGRAMS
(R-23-1-MAM)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS
DEPARTMENT OF HEALTH

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As amended:

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the provisions of section 42-35-4.1 of the
Rhode Island General Laws, as amended)**

INTRODUCTION

These amended *Rules and Regulations Pertaining to Quality Assurance Standards for Mammograms (R23-I-MAM)* are promulgated pursuant to the authority conferred under Chapters 5-37; 23-17; 27-19; 27-20; 27-41 and 42-62 of the General Laws of Rhode Island, 1956, as amended and are established for the purpose of adopting quality standards for taking, processing and interpreting mammograms in this state.

In accordance with the provisions of section 42-35-3(c) of the General Laws of Rhode Island, 1956, as amended, in the development of regulations, consideration was given to: (1) alternative approaches to the regulations; (2) duplication or overlap with other state regulations; and (3) any significant economic impact on small business as defined in Chapter 42-35 of the General Laws. Based on the available information, no known alternative approach, duplication or overlap was identified. The health, safety and welfare of the public overrides any economic impact which may be incurred from these proposed regulations.

These rules and regulations shall supersede any previous rules and regulations related to the adoption of quality assurance standards of mammograms promulgated by the Rhode Island Department of Health and filed with the Rhode Island Secretary of State.

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PART I DEFINITIONS AND GENERAL REQUIREMENTS

Section 1.0 Definitions

Wherever used in these rules and regulations, these terms shall be construed as follows:

- 1.1 ***"Director"*** means the Director of the Rhode Island Department of Health.
- 1.2 ***"Department"*** means the Rhode Island Department of Health.
- 1.3 ***"Health care facility"*** means those facilities subject to licensure by the Department of Health in accordance with the provisions of Chapter 23-17 of the General Laws of Rhode Island, 1956, entitled "Licensing of Health Care Facilities", and as defined by regulations adopted thereunder.
- 1.4 ***"Mammography"*** is the radiologic examination of the breasts. This can be for screening, diagnostic or stereotactic purposes:
 - a) Screening mammography is the radiologic examination of the breasts of women with no breast symptoms, for the purpose of detecting x-ray evidence suggestive of breast cancer. The examination is limited to two (2) radiographic views per breast, and a definitive pathologic diagnosis is not rendered.
 - b) Diagnostic mammography is a procedure which is carried out on women with breast signs or symptoms or an abnormal screening mammogram, and is performed to characterize lesions to the fullest extent possible.
 - c) Stereotactic breast biopsy is a procedure using radiographic equipment to localize an area which can be seen mammographically and to guide the biopsy with a needle. Equipment employed may be a vacuum-assisted device or a needle for fine needle aspiration.
- 1.5 ***"Non-referred patient"*** means any patient who presents for screening mammography without a referral from a physician.
- 1.6 ***"Provider"*** means any physician, hospital, or other person licensed or otherwise authorized in this state to furnish health care services and who meets the applicable FDA/ Mammography Quality Standards Act (MQSA) regulations and/or the voluntary requirements of the American College of Radiology (ACR) Stereotactic Breast Biopsy Accreditation Program.
- 1.7 ***"Physician"*** means an individual licensed to practice medicine or osteopathy pursuant to the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended.
- 1.8 ***"Quality assurance program"*** means a program to consistently ensure state of the art performance by physicians, and other personnel, for taking, processing and interpreting mammograms.

- 1.9 ***"Person"*** means an individual, trust or estate, partnership, corporation (including, but not limited to associations, joint stock companies, limited liability companies and insurance companies,) state, or political subdivision or instrumentation of a state.
- 1.10 ***"Radiographer"*** means any person licensed by the state of Rhode Island to perform radiography (the direct application of ionizing radiation to a person for diagnostic purposes).
- 1.11 ***"Radiation Control Agency"*** means the office within the Department of Health responsible for the promulgation and enforcement of the *Rules and Regulations for the Control of Radiation (R23-1.3RAD)*.

Section 2.0 General Requirements

- 2.1 Set forth herein are quality assurance standards issued by the Director of Health for taking, processing and interpreting mammograms in the state of Rhode Island.

PART II QUALITY ASSURANCE STANDARDS

Section 3.0 Administrative Requirements

3.1 A designated physician, who meets the qualifications specified in section 4.0 herein, shall be responsible for the comprehensive over-all quality assurance program in each facility where mammograms are performed. Each quality assurance program shall include methods to ensure state-of-the art performance by personnel and maximal operation of equipment, with the ultimate objective of providing the highest quality medical care possible to the patient.

3.3.1 The quality assurance program shall ensure at a minimum:

- a) Credentialing of all personnel in accordance with all applicable regulations;
- b) Compliance with technical requirements of section 5.0 herein.
- c) Systematic record keeping; and
- d) Compliance with follow-up as indicated in section 6.0 herein.

3.2 The facility shall meet the basic requirements of the voluntary ACR Stereotactic Breast Biopsy Accreditation Program in each facility where stereotactic breast biopsies are performed.

Section 4.0 Personnel Requirements

4.1 Requirements for Physicians:

The physician who is taking or interpreting mammograms or performing stereotactic breast biopsies shall:

- 4.1.1 Meet the requirements of the FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotactic Breast Biopsy Accreditation Program.
- 4.1.2 Interpret the minimum number of mammograms, as specified in the FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotactic Breast Biopsy Accreditation Program.
- 4.1.3 Meet ongoing continuing medical education consistent with FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotactic Breast Biopsy Accreditation Program.
- 4.1.4 Be licensed in Rhode Island and be available for in-person consultation in Rhode Island with any physician. This function may be carried out by another radiologist with whom s/he is in practice and who meets the qualifications of section 4.0 herein to interpret mammograms.
- 4.1.5 Submit mammography films to the Rhode Island Department of Health for review on a periodic basis. These films will be selected at the Department's discretion.
- 4.1.6 Be responsible for accepting or rejecting the quality of all images s/he is interpreting.

4.2 Requirements for Radiographers:

- 4.2.1 Any radiographer operating an x-ray system used to perform mammograms shall comply with, at a minimum, the following training and experience requirements:
- a) Possession of a Registered Technologist (RT) Certification by the American Registry of Radiologic Technologists (ARRT) as a radiographer;
 - b) Completion of orientation in the mammographic facility's procedures and policies; and,
 - c) Documentation of mammography training through continuing education programs or on the job training to radiation safety, radiation protection, technical factors, breast positioning and quality control.
- 4.2.2 Any radiographer operating a mammographic x-ray unit shall be licensed in Rhode Island in accordance with Chapter 5-68 of the General Laws of Rhode Island, as amended.
- 4.2.3 The radiographer shall meet the requirements of the FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotactic Breast Biopsy Accreditation.

Section 5.0 Technical Requirements

5.1 Purpose and Scope

- 5.1.1 This part establishes technical requirements for X-ray systems, X-ray film processors, phantom imaging, mammography operator training, measurement of mammographic doses and establishment of quality assurance programs at all facilities providing mammographic imaging services.
- 5.1.2 In addition to the requirements of this part, all facilities providing mammographic imaging services must comply with the provisions of Part A, Part B and Subparts F.2, F.3 and F.5 of the Rhode Island *Rules and Regulations for the Control of Radiation*.

5.2 Mammography System Requirements

- 5.2.1 X-ray System Requirements: All X-ray systems used for mammographic imaging shall comply with, at a minimum, the following technical specifications:
- a) The X-ray system shall be equipped with compression devices which effectively immobilize the breast.
 - b) The X-ray system shall meet target and filtration requirements of the applicable FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotatic Breast Biopsy Accreditation Program.

- c) The X-ray system focal spot size shall meet the requirements of the applicable FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotactic Breast Biopsy Accreditation Program.
- d) The X-ray system shall have the capability of using anti-scatter grids which have been specifically designed for the mammographic (film/screen) imaging modality being utilized.
- e) All X-ray systems purchased on or after December 1, 1990 shall have the capability of automatic exposure control (AEC) for all film/screen imaging modalities.
- f) All x-ray systems used for stereotactic breast biopsy shall meet the applicable FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotatic Breast Biopsy Accreditation Program.

5.2.2 X-Ray Film Processor Requirements: Each mammography facility shall ensure that any X-ray film processor used for processing mammographic images at said facility is in compliance with, at a minimum, the following technical requirements:

- a) The processing parameters (e.g. processing temperature, cycle time, replenishment, etc.) shall be optimized to meet the manufacturer's requirements for the specific film being used for mammographic imaging.
- b) The processing parameters shall be commensurate with the workload of the facility to ensure processing with viable chemistry.

5.2.3 Phantom Imaging Requirements: The phantom images shall meet the applicable FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotactic Breast Biopsy Accreditation Program.

5.3 Measurement of Mammographic Dose

5.3.1 Measurement of Average Glandular Dose

- a) The average glandular dose for one (1) craniocaudal view of a 4.5 centimeter compressed breast fifty percent (50%) adipose and fifty percent (50%) glandular tissue shall be measured by a person registered with the state Radiation Control Agency as a diagnostic medical physicist qualified to provide radiological physics services. This measurement shall be made:
 - (1) Prior to the first use of the unit for mammographic imaging of humans;
 - (2) Following each replacement of the X-ray tube;
 - (3) Following any repair or replacement of major X-ray system components that may affect the output of the X-ray tube; and

- (4) At intervals not to exceed one (1) year.
- b) The average measured glandular dose per view shall not exceed the following parameters:
 - (1) 100 millirad (1.0 mGy) for film screen units without grids; or,
 - (2) 300 millirad (3.0 mGy) for film/screen units with grids, or for stereotactic breast biopsy.
- c) The written record of the results of all measurements required by section 5.3.1(a) above shall be maintained and shall include, as a minimum, average glandular dose, the name of the person performing the measurements, the date the measurements were performed, identification of the phantom(s) used to obtain such results, and the technique factors used to determine such results. Results of these measurements shall be posted where any mammographic operator shall have ready access to such results while operating the mammographic X-ray unit and also filed with the records required by Paragraph F.2.13(e) of the Rhode Island *Rules and Regulations for the Control of Radiation*.

5.4 Evaluation of the Adequacy and Effectiveness of the Imaging Program

5.4.1 Technical evaluation aspects specific to mammography facilities:

- a) Each facility shall develop and implement an ongoing quality assurance program specific to mammography.
 - i) The quality assurance program shall be developed and conducted by a physician, as qualified in section 4.0 herein, in conjunction with a person registered with the state Radiation Control Agency as a diagnostic medical physicist and who is qualified to provide radiological physics services.
 - ii) This quality assurance program shall be performed by an ARRT registered radiologic technologist who has had specific training, which is acceptable to the state Radiation Control Agency, which covers quality assurance procedures for both the radiographic and processing systems.
- b) The quality assurance program shall also include a written procedures manual which describes in detail the tests to be performed, the frequency for each test, the criteria for acceptability of each test and the actions to be taken when test results are outside the established criteria. A log shall be kept listing the results of all quality assurance testing and the actions taken to correct any problems uncovered by testing.
- c) The quality assurance program shall be reviewed by a physician, as qualified in section 4.0 herein, in conjunction with a person registered with the state Radiation Control Agency as a diagnostic medical physicist, qualified to provide radiological physics services. This review shall take place at intervals not to exceed one (1) year and shall be documented in writing.

- d) The minimum quality assurance testing parameters and frequencies are listed in Appendix A, herein.
- e) The quality assurance program shall meet the applicable FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotatic Breast Biopsy Accreditation Program.

Section 6.0 Record Keeping Requirements

Each mammographic screening, diagnostic and stereotactic breast biopsy site must designate a physician who meets the qualifications specified in section 4.0 above, to be responsible for the maintenance of records and files, as listed herein.

6.1 Logs, Referral and Record Retention:

6.1.1 At a minimum, the physician shall:

- a) Have documentation of written policies and procedures pertaining to notification of the patient's physician of the mammogram results. All reports in the "high probability" category shall be communicated to the referring physician or his/her designated representative by telephone, by certified mail, or communicated in such a manner that receipt of the report is ensured and documented.
- b) Clearly document numbers of screening, diagnostic and stereotactic procedures performed.

6.1.2 Mammography sites shall have an operational system in place to maintain records concerning:

- a) correlation of positive mammograms to biopsies performed; and,
- b) numbers of cancers detected.

6.1.3 Referrals/follow-up for non-referred cases:

- a) Mammography facilities which elect to accept non-referred patients must have well-developed notification procedures for the patient and her physician or procedures for referral to a qualified physician who has agreed to accept such patients.
- b) The physician or his/her associate who originally interprets the film of a non-referred patient is responsible for ensuring that follow-up has taken place.

6.1.4 Film and Reports retention:

- a) Pursuant to section 23-4.9-1 of Rhode Island General Laws, as amended, every physician, surgeon, hospital, health maintenance organization or any other health care facility or person

that takes a mammography x-ray of any individual within this state shall keep and maintain that mammography x-ray for the known life of the individual.

- b) Any such x-ray may be destroyed if the individual has had no contact with the physician, surgeon, hospital, health maintenance organization, or other health care facility or provider for a period of fifteen years or greater.

6.2 **Internal Audit:** A designated physician who meets the qualifications specified in section 4.0 herein shall include as part of an internal audit:

- 6.2.1 Evaluation of Retakes: Each mammography facility shall conduct an ongoing retake analysis (i.e. monthly or quarterly).
- 6.2.2 Quality Assessment: Each mammography facility shall establish a method to assess the quality of its mammographic interpretations by correlating mammographic findings with histology.
- 6.2.3 Oversight of the radiographer who implements all quality assurance activities specific to mammographic imaging, as indicated in section 5.0 of these regulations.

Section 7.0 Severability

- 7.1 If any provision of these rules and regulations or the circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the regulations are declared to be severable.

APPENDIX A

MINIMUM QUALITY ASSURANCE TESTING PARAMETERS AND FREQUENCIES

A. X-RAY EQUIPMENT PARAMETERS:

The following X-ray equipment parameters must be checked after any changes in exposure technique and/or imaging modality, major repair/replacement of X-ray system components, as required by section 5.0 of these regulations, and at intervals not to exceed one (1) year. In addition, the applicable FDA/MQSA regulations and/or the voluntary requirements of the ACR Stereotatic Breast Biopsy Accreditation Program shall be followed.

1. Measurement of Average Glandular Dose
2. Half-value Layer
3. Accuracy And Reproducibility of Kvp Stations
4. Accuracy And Reproducibility of Timer Stations (If Applicable)
5. Linearity And Reproducibility of Ma Stations (If Applicable)
6. Reproducibility of X-ray Output in Aec And Manual Modes
7. Accuracy of Source-to-film Distance Indicators (If Applicable)
8. Light/x-ray Field Congruence (If Applicable)
9. Accuracy of Thickness Indicator on Compression Device
10. Verification of Back-up Timer For Aec Operation

B. PROCESSOR PARAMETERS:

I. The following film processor parameters must be checked at intervals not to exceed those specified below:

	PARAMETER	FREQUENCY
1.	Speed Index Consistency	Daily
2.	Contrast Index Consistency	Daily
3.	Base plus Fog Consistency	Daily
4.	Developer Solution Temperature	Daily
5.	Film Fogging, Light Leaks and Safelight Filter Condition and Location	Six (6) Months

- | | | |
|----|-----------------------------------|-------------------------------------------|
| 6. | Processor Artifact Identification | Continuous Manufacturers' Recommendations |
| 7. | Processor Maintenance/cleaning | Continuous Manufacturers' Recommendations |

C. EQUIPMENT CONDITION PARAMETERS:

The following equipment condition parameters must be checked at intervals not to exceed those specified below:

	PARAMETER	FREQUENCY
1.	Screen Condition Evaluated	Daily
2.	Screens Cleaned	As required
3.	Screen /Film Contact Evaluated	Semi-annually and when changed
4.	Screen Artifact Identification	Continuous
5.	View Box Light Output Consistency Between View Boxes and over Time	Annual
6.	Label Cassettes	On receipt and as needed

D. SYSTEM CHECKS:

The following system checks must be performed at intervals not to exceed those specified below:

	PARAMETER	FREQUENCY
1.	Phantom Imaging	Initial baseline and after major repair or change in film/screen
2.	Comparison of Phantom Image Quality to Initial Baseline and Minimum Phantom Imaging Criteria	As required by applicable FDA/MQSA regulations and/or voluntary requirements of the ACR Stereotactic Breast Biopsy Accreditation Program.